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Indiana State Department of Health

An Equal Opportunity Employer

Reporting Complications from Surgical Treatment for Morbid Obesity Rule 410 IAC 28 (LSA Document #06-139)

Economic Impact Statement **pursuant to IC 4-22-2.1**

July 27, 2006

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

The Indiana State Department of Health (ISDH) estimates that at least 30 physicians perform surgical treatments for treatment of morbid obesity in Indiana.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

Precise cost estimates are difficult to make due to the variances in organizational structure and employee compensation schedules among the various providers. The ISDH expects that some of these functions are already performed by the centers which will decrease the additional time or cost to comply with the rule. The following are the estimated annual costs resulting from the proposed rule:

The reporting required by the proposed rule is based on a physician's post-surgical monitoring of patients for whom the physician provided surgical treatment for morbid obesity. The rule will not impact that monitoring. The rule does require, however, that those physicians report any deaths or serious complications experienced by those patients.

In 2003, Indiana hospitals reported over 2,500 surgical treatments for morbid obesity (bariatric procedures). There has been an increase in the number of surgeries reported over the last six years. The data do not indicate which procedures might qualify as a surgery requiring reporting of death or serious complication. For purposes of projecting costs, we assume 3,000 surgeries annually for the surgical treatment of morbid obesity in Indiana.

Nationally, surgical procedures have a death rate of between 0.8 and 8 percent (in 2003, Indiana hospitals reported 7 deaths and 2,540 bariatric surgeries for a death rate of less than 0.3%) and a complication rate of approximately 7.5 percent for complications requiring immediate intervention. If we apply those rates to the projected 3,000 surgeries requiring reporting, we project the following number of reports:

The ISDH projects the following number of reports for waist circumference:

Period Covered	Surgeries	Waist Circumference Reports	Total Reports
07/01/2007 thru 12/31/2007	1,500	Assume 4 reports per patient: at time of surgery, 30, 60, and 90 days post	6,000
01/01/2008 thru 12/31/2008	3,000	Assume 5 reports per patient: at time of surgery, 30, 60, 90 days, and at 1 year post	15,000
01/01/2009 thru 12/31/2009	3,000	Assume 5 reports per patient: at time of surgery, 30, 60, 90 days, and at 1 year post	15,000
01/01/2010 thru 12/31/2010	3,000	Assume 5 reports per patient: at time of surgery, 30, 60, 90 days, and at 1 year post	15,000
Total	10,500		51,000

These reports can be compiled from each patient's medical records.

The ISDH projects the following number of reports for deaths, serious side effects, and major complications:

Period Covered	Surgeries	Deaths (assuming 1% death rate)	Serious Side Effects/Major Complications (assuming 7.5% complication rate)	Total Reports
07/01/2007 thru 12/31/2007	1,500	15	115	130
01/01/2008 thru 12/31/2008	3,000	30	225	255
01/01/2009 thru 12/31/2009	3,000	30	225	255
01/01/2010 thru 12/31/2010	3,000	30	225	255
Total	13,500	135	675	810

Assuming that: 1) there are no more than 15,000 reports per year and 2) the ISDH is not required to perform any analysis of the data or make summary reports from the data, the ISDH projects the amount of time for the Agency to collect and maintain the reports is de minimus and can be absorbed in current Agency operations.

Fiscal Impact to Physicians Performing Surgical Treatment for Morbid Obesity

The ISDH estimates the time to prepare the required data report on waist circumference to be one hour or less. The completion of the form may involve time from the physician as well as from the medical records or nursing staff. The average estimated cost for each semiannual report of waist circumference for all morbid obesity surgical patients from each physician is \$150. Assuming 30 physicians report waist circumference data on morbid obesity surgical treatment patients, the annual cost would be \$4,500. The individual physician's cost will depend on the number of patients treated.

The reporting of deaths, serious side effects, and major complications will require more time from the physician as well as from the medical records staff. Assuming \$150 per death, serious side effect, or major complication reported, the annual reporting costs for physicians subject to reporting requirements are projected to be \$33,750, based on the above assumptions exclusive of inflationary factors. The individual physician's cost will depend on the number of patients treated and the incidence of death or serious complication.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

Based upon the data and estimates presented, the total annual economic impact going forward on an annual basis will be \$38,250, exclusive of inflationary factors. The individual physician's cost will depend on the number of patients treated and the incidence of death or serious complication.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

IC 16-40-3 requires physicians who perform surgical treatment for the treatment of morbid obesity to report waist circumference for each patient at the time of surgery, 30, and 90 days post surgery, and at one year. The proposed rule adds a report of waist circumference at 60 days to provide another data point for tracking waist circumference changes. The law also requires physicians who perform surgical treatment for morbid obesity to report deaths, serious side effects, or major complications to the ISDH. The physicians are required to report twice each year, June 30 and December 31. Additionally, IC 16-40-3 as added sets forth the requirements for agency rules. The ISDH believes the proposed rules are within the requirements established in IC 16-40-3.

5. Regulatory Flexibility Analysis

A. Establishment of less stringent compliance or reporting requirements for small businesses.

IC 16-40-3 makes no provisions for waiving the reporting requirements or changing the reporting requirements provided in the law.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

IC 1-40-3 established the reporting requirements for physicians and provides no provisions for waiving or changing those requirements.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

The rules drafted provide for the minimum amount of data needed to fulfill the requirements of the law. There are no other reporting requirements imposed by the proposed rule.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

IC 16-40-3 mandates reporting of data. It does not regulate the performance of surgical procedures for the treatment of morbid obesity.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The statute provides no waiver or exemption for the reporting of death or serious complication after surgical treatment for the treatment of morbid obesity.

Conclusion:

SEA 255 amended IC 16-40, which requires physicians who provide surgical treatment for the treatment of morbid obesity to report waist circumference for each patient at the time of surgery, 30, 60, and 90 days post surgery, and at one year; and to report deaths, serious side effects, or major complications to the ISDH. The physicians are required to report twice a year, June 30 and December 31, to the ISDH. The rules do not change medical practice for monitoring patients after the provision of surgical treatment for the treatment of morbid obesity, only the reporting of defined events after that surgical treatment. The statute provides no waiver or exemption for the reporting of death or serious complication after surgical treatment for the treatment of morbid obesity.